United States Court of Appeals

for the Second Circuit

APPELLANT'S REPLY BRIEF

ORIGINAL

76-6135

To be argued by
MILTON A. BASS

In The

United States Court of Appeals

For The Second Circuit

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR, CO., INC.,

Plaintiffs-Appellants,

vs.

F. DAVID MATHEWS, Secretary of Health, Education and Welfare and ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs,

Defendants-Appellees.

On Appeal from the United States District Court for the Southern District of New York.

REPLY BRIEF FOR PLAINTIFFS-APPELLANTS

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I N D E X

CASES CITED

STATUTES, REGULATIONS AND OTHER AUTHORITIES CITED

Statutes

Regulations

Other Authorities Cited

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

Docket No. 76-6135

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THE NATIONAL NUTRITIONAL FOODS ASSOCIATION and SOLGAR CO., INC.,

Plaintiffs-Appellants,

-v-

DAVID F. MATHEWS, Secretary of Health, Education and Welfare, and ALEXANDER M. SCHMIDT, Commissioner of Food and Drugs,

Defendants-Appellees.

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REPLY BRIEF FOR PLAINTIFFS-APPELLANTS

Introduction

Plaintiffs-appellants respectfully submit the instant reply brief in response to the brief filed herein by defendants-appellees. Appellees in their brief have in certain material respects misstated and misconstrued the prior history of these proceedings. Fundamentally, appellees fail to recognize the requirements of the Federal Food, Drug, and Cosmetic Act as interpreted by this Court. Appellees have further completely disregarded the nature and requirements of an Overton-type

hearing which was directed to be held by this Court after the prior appeal.

1.

RELIANCE ON THE UNITED STATES PHARMACOPEIA AND NATIONAL FORMULARY FOR DRUG CLASSIFICATION HAS ALREADY BEEN REJECTED BY THIS COURT AND THE DISTRICT COURT

The agency advances once again as an explanation for drug classification of vitamins A and D at the regulated levels, the fact that both of these vitamins are listed in the United States Pharmacopeia and National Formulary. The agency claims that the United States Pharmacopeia lists these vitamins for both nutritional and therapeutic purposes and that these distinctions are therefore binding as a matter of law under the Federal Food, Drug, and Cosmetic Act. It is the agency's position that because the USP lists certain levels of vitamins A and D for nutritional purposes,[1] anything beyond those levels may be regulated by the agency as a drug.

Appellees have once again advanced this rationale, albeit in a slightly altered form, despite the fact that it has already been rejected twice by this Court as well as by the District

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1 See also discussion in Appellants' main brief, p.23, n.17, 28 as to Appellees' confusion of the statutory requirements by improperly equating the alleged absence of nutritional use with an absence of food use.

Court on remand. Moreover, this rationale has been expressly negated by the new vitamin and mineral legislation, §411 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §350.

It is respectfully submitted that Appellees' reliance on the USP is dispositively answered by the newly enacted vitamin and mineral legislation. Under the USP rationale, the agency is seeking to classify the products as drugs because their potency exceeds the levels of nutritional usefulness which are recognized in the USP. The new statute expressly prohibits the Commissioner from classifying any product as a drug on the basis that it exceeds the levels at which the Commissioner feels the product is nutritionally useful. Here the Commissioner is now trying to use the levels in the USP (which, incidentally, are identical to those listed in the U.S. RDA's) as his yardstick for that particular purpose. The statute expressly prohibits a finding of drug classification on such a basis and for that reason alone, this latest effort to rely on the USP for nutritional levels beyond which vitamins A and D could be sold as foods, is invalid, and should be rejected.

Furthermore, Appellees' rationale is also invalid under the principles laid down earlier by this Court in dealing with the very same issue. In Judge Friendly's decision, this Court took note of the fact that "all the vitamins and presumably all the minerals with which we are here concerned are

recognized in the official United States Pharmacopeia or the official National Formulary." 504 F.2d at 788-789. This Court rejected the agency argument in terms of the USP and NF in connection with the general vitamin regulations on the grounds that it was both impermissible as a post hoc rationalization as well as clearly invalid in light of the fact that it ran counter to the regulations which were being promulgated. This Court, on the prior appeal in this matter, did not accept this approach, although Appellees argued the very same theory before this Court.

Once again, this attempted rationale is clearly an improper post hoc rationalization. Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962); U.S. ex rel Checkman v. Laird, 469 F.2d 773 at 780 (2d Cir. 1972); NLRB v. Clark, 468 F.2d 459, 467 (5th Cir. 1972); NLRB v. Groendyke Transport, Inc., 372 F.2d 137, 141 (10th Cir. 1967); SEC v. Chenery Corp., 318 U.S. 80, 87 (1943); National Nutritional Foods Association v. Food and Drug Administration, 504 F.2d 761 at 788-789 (2d Cir. 1974); National Nutritional Foods Association v. Mathews, 418 F.Supp 394 at 398 (S.D.N.Y., 1976).

In any event, the rationale is invalid and does not have merit. Contrary to the assertion in Appellees' brief, page 30, that this issue was not previously ruled upon, it has long been established that listing of products in the USP or NF does not automatically determine drug status under the Act. In AMP Incorporated v. Gardner, 275 F.Supp. 410 (S.D.N.Y., 1967), aff'd, 389 F.2d 825 (2d Cir. 1968), the court rejected the same agency's

contention that a product was a drug (rather than a device) merely because it was listed in the USP.[2] See also Federal Trade Commission v. Liggett & Meyer Tobacco Company, 108 F.Supp 573 (S.D.N.Y., 1952) where the listing of tobacco in one of the pharmacopeias was not found to be sufficient to automatically classify tobacco as a drug.

The general approach to drug classification, suggested by Appellees' argument, would clearly lead to absurd results. Water is listed in the USP immediately after Vitamin A Capsules, along with olive oil, common salt (sodium chloride), as well as peanut oil. (JA 207a, 208a, 210a, 211a, 212a). It is obvious that Congress never intended that these products should be considered as drugs when they are not used for a therapeutic purpose, merely because they are listed in one of the compendia.

All of the cases cited by Appellees at page 31 of their brief, which referred to the official compendia, involved situations where the product was in fact being sold for drug purposes. None of these cases involved a situation where the drug status of the product was determined exclusively by reference to the compendia. Clearly, the listing as a drug in the compendia does not preclude food use under the Act. As this Court has previously noted, actual objective intent of the manufacturer in

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2 Appellees' brief relies on the Appellate Court's decision in the AMP case. Such reliance is completely misplaced. This Court's decision in AMP did not discuss at all the question of the permissibility of relying on the compendia for the purpose of drug classification. See 389 F.2d at 830 where this Court emphasized that the "intended use" element is controlling as to drug definition.

connection with his representations as to the use of the product, is essential for the purpose of determining drug as opposed to food status in any given case. (504 F.2d 788-789; 512 F.2d 701-703).

Appellees' latest effort to rely on the official compendia involves the claim that the products are drugs because they exceed the nutritional levels mentioned in the USP. This is an unauthorized attempt by the agency to automatically rely on the prophylactic (i.e., nutritional) levels suggested in the USP. The statute, however, does not confer on these compendia any authority with respect to determining food or nutritional requirements. As such, the level proposed in the compendia for nutritional purposes do not have any independent legal status or effect. Furthermore, the invalidity of this attempt to rely on the USP prophylactic levels is evident since the levels set forth (8000 and 400 I.U. respectively) are identical with the levels in the U.S. RDA's, which were established by the general regulations. In fact, this Court may take judicial notice of the fact that nutritional levels are set forth in the USP for all of the vitamins in that compendium and that, not surprisingly, they too are in accord with the conservative levels set forth in the U.S. RDA's.[3] Since these levels are identical, in effect, Appellees are once again seeking to classify products as drugs

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[3] The record in this proceeding also shows that the FDA and the drafters of the USP collaborate closely with respect to these matters. (See JA 498a-501a)

because they exceed the conservative nutritional levels as set forth in the U.S. RDA's. This is precisely the rationale which was invalidated by Judge Friendly with respect to 21 C.F.R. §125.1(h). By merely changing the nomenclature, and using the USP as a reference point for the same levels of suggested nutritional usefulness, Appellees cannot bypass the findings and rulings of this Court.

Contrary to the assertion in Appellees' brief, such reliance on the USP would once again contradict the agency's own regulations. Even under the newly revised general vitamin regulations [41 F.R. 46156 et seq. (October 19, 1976); see also 40 F.R. 23246, cols. 2 and 3 (May 28, 1975)], the agency permits the sale as food products of any and all vitamins and minerals in any safe quantity even if they are in excess of the levels set forth in the U.S. RDA s and the USP. For example, the United States Pharmacopeia lists the nutritional level for vitamin C at 60 mg. This is, once again, the same level as that also established in the U.S. RDA's. This Court previously noted that there was no reason why a 500 mg. pill of vitamin C, which was frequently sold, could not be used for nutritional purposes in accordance with differing views as to nutrition. 504 F.2d at 783. The agency's approach of attempting to use the USP for drug classification would therefore have the effect of classifying as a drug all vitamins and minerals, not limited to vitamins A and D, above the levels recognized in the USP for nutritional purposes. This is clearly in conflict with Judge Friendly's ruling in this case, as well as the agency's own approach with respect

to the other vitamins and minerals.

The simple answer to Appellees' reliance on the USP is that Congress never intended the official compendia to be used for automatic drug classification, as opposed to food classification, let alone for dispositive determination of nutritional requirements. Consequently, the remand by this Court to the District Court was framed in terms of findings of objective intent on the part of manufacturers and not in terms of the nutritional views which might be incidentally expressed in one of the compendia.

It may be noted that the District Court in rejecting this very argument advanced by Appellees, because it was a clear post hoc rationalization, nevertheless felt that the argument had weight, because otherwise the District Court did not see what relevance the inclusion of §201(g)(1)(A) would have in terms of drug classification (JA 572a). It is respectfully submitted that the District Court erred in this respect because it did not take into account the full definitional structure under the Food and Drug Act. The emphasis in §201(g)(1)(A) which makes reference to the compendia, is the fact that the articles are "recognized" in these compendia for drug purposes. This concept of recognition plays a very important role in terms of the distinction to be made as far as articles which are defined as "new drugs" under the statute.

Under §201(p)(1) [21 U.S.C. §321(p)(1)] "new drugs" are defined as being products which are not generally "recognized" among experts as being safe and effective for their intended

purpose. The purpose of including the reference to the various compendia in §201(g)(1)(A) was to establish them as officially "recognized" compendia, for this purpose. Obviously, if a drug is recognized in one of the official compendia, it is not a "new drug" under the statute which deals with the absence of such recognition. "Recognition" in one of the compendia, however, should not be taken to impose drug status when the product is not "intended" for drug use at all. It is respectfully submitted that a reading of §201(g)(1)(A) in conjunction with §201(g)(1)(B) shows that the purpose of making reference to the compendia was for the purpose of distinguishing between "drugs" and "new drugs" under §201(p)(1) and not for the purpose of imposing automatic drug classification on any article listed in the compendia, irrespective of its actual intended use.[4]

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[4] In fact, the legislative history of the Act shows that the inclusion of the reference to the compendia was controversial because at that time it was feared that only articles recognized in the compendia would be permitted to be sold as drugs. The sponsors of the Food and Drug Act pointed out that although these were officially recognized drugs, other drugs would be permissible under the other provisions of the statute. See Dunn, Federal Food, Drug, and Cosmetic Act, A Statement of Its Legislative Record, pp. 111, 167, 192, 214, 239, 302-304 (1938).

2.

APPELLEES SEEK TO REARGUE THE DECISION OF THIS COURT AS TO OBJECTIVE INTENT OF MANUFACTURERS AS DETERMINING DRUG CLASSIFICATION

Appellants' main brief (pp. 6-9) sets forth in full the rulings of this Court as to drug classification in terms of intended use of the product. Appellees' brief (p. 33) takes the position that objective evidence of intent "is not and cannot be dependent upon the seller's or consumer's intent." Aside from the fact that this illogical proposition leaves us with no one's intent to consider, it is directly contradictory to the rulings of this Court which were made by both Judge Friendly and Judge Mansfield, as well as in direct contravention of the legislative history of the Food and Drug Act.[5]

Appellees' position on this appeal, as well as in the District Court, demonstrates once again that the agency has completely failed to take into account or even consider what the actual intent of the manufacturers of these products was. Instead, the agency on the remand abandoned the claim that manufacturers were making therapeutic claims (JA 528a-530a) and now seeks to rely on an abstract drug classification totally divorced from any considerations of actual objective intent. Judge Friendly's decision holds that a court should be free to pierce a manufacturer's

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[5] Appellees' brief (p.32) concedes that Judge Friendly's decision holds that the seller's intent is the crucial element. Judge Mansfield noted that the agency had failed to make a finding as to the intent of manufacturers. 512 F.2d at 703.

claims and find objective intent in a proper case. (504 F.2d 789) Appellees instead, seek to transform the objectivity standard into a mechanism for dispensing with any consideration of the manufacturer's actual objective intent.

The foregoing serves to highlight the fact that the agency in these regulations sought to regulate as drugs products which were in fact being sold in good faith by manufacturers for food purposes. The existence of differing nutritional views as to optimum daily requirements for vitamins had already been noted by appellants (and disregarded by appellees). See Appellants' main brief pp. 24-25.

As a specific example, the attention of the Court is respectfully directed to a typical multi-vitamin product, the label for which was inserted in the record for these proceedings by the government (JA 241a). This label sets forth a typical dietary supplement formula which includes 25,000 I.U. of vitamin A and 1,000 I.U. of vitamin D. A review of this label and the formulation of the product clearly shows that there can be no question but that the product was "intended" for food use under the provisions of the Federal Food, Drug, and Cosmetic Act. The agency specifically sought in these regulations to prohibit these products by expressly noting that the regulations were intended to apply to dietary supplements (JA 36a, cols. 1 and 2). Appellees now claim that the regulation was intended to apply only to drug products (Appellees' brief, p. 45). The answer to this contention is that the regulations do not so state. Unlike other

regulations of this type, the vitamin A and D regulations fail to specify that they apply only to drug preparations.

Appellees also persist in confusing food use with and limiting it to the conservative levels recognized in the U.S. RDA and the USP. The fundamental error in the agency's position is that the agency has and continues to disregard the fact that manufacturers can sell these products in good faith for food use and that the agency has declined to even consider what the good faith intent of any or all manufacturers was.

The agency's failure in this regard is further buttressed by the absence of evidence of 10,000 I.U. and 400 I.U. of vitamins A and D, respectively, as levels for therapeutic usage. Commissioner Schmidt's affidavit merely states that he has been aware of therapeutic usages for these vitamin A and D products at "high dosages" (JA 320a), thereby deliberately avoiding a specification of the exact level at which these products have been used expressly for therapeutic purposes. In fact, the material submitted by the Commissioner show that the threshold therapeutic level for vitamin A was considered to be at 25,000 I.U. (JA 344a, 404a); for vitamin D, the threshold therapeutic level for infants was considered at 1,200 I.U. (JA 350a); while for adults, the threshold level was considered at 10,000 I.U. of vitamin D (JA 346a), or even higher (JA 430a). In contrast the record shows that manufacturers were selling vitamin A and D products in dosages lower than even the threshold therapeutic levels indicated

by the record (JA 232a)[6]

The agency clearly could not comply with Judge Mansfield's direction (512 F.2d 703) that vitamins A and D at the levels of 10,000 I.U. and 400 I.U., respectively, be shown to have been used "almost exclusively" for therapeutic purposes. Indeed, no therapeutic uses at these levels have been shown at all and in fact non-therapeutic food uses have been demonstrated in the record despite the agency's attempt to disregard them.

3.

APPELLEES HAVE MISSTATED THE RELATIONSHIP BETWEEN THE VITAMIN A AND D REGULATIONS AND THE GENERAL VITAMIN REGULATIONS

Appellees' brief seeks to make various distinctions between the general vitamin regulations and the instant vitamin A and D regulations. Many of these attempted distinctions are incorrect. For example, Appellees' brief, (p. 7), seeks to characterize the attempted drug definition in 21 CFR §125.1(h) as applying to all

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6 One of the examples of the dangers of post hoc rationalizations by counsel is indicated in appellees' brief p. 40, where the suggestion is made that as little as 1,000 I.U. of vitamin A was used therapeutically. The reference to 1,000 I.U. in the article quoted at appellees' brief, p. 40, is an apparent misprint. 1,000 I.U. is only 25% of the U.S. RDA and can hardly be a therapeutic level. The record shows that in connection with the various conditions mentioned in that article, the threshold level of recommended use was in fact 100,000 I.U. of vitamin A (see e.g., Exh. Vol. 1 at E200, E267, E345). Once again, the fact that the Commissioner was not made available for examination hinders the judicial effort for arriving at accurate information in these proceedings.

products, including breakfast cereals and milk, while characterizing the vitamin A and D regulations as applying only to these two vitamins and only when they are produced in the form of capsules or tablets.

Appellees clearly do not understand their own regulations. As noted in Appellants' main brief (p. 29, n.25), the regulations apply also to products where vitamins A and D were merely components of an overall dietary supplement. (See also, JA 241a). In addition, as part of the general vitamin regulations, 21 CFR §80.1(a) provides:

> "The dietary supplements of vitamins and/or minerals for which definitions of standards of identity are prescribed by this section are prepared and offered as tablets, capsules, wafers or other similar uniform units;..." (emphasis added) 41 F.R. 46170, col. 3 (October 19, 1976).

The agency itself thereby recognizes that dietary supplements in capsule or tablet form are foods under the statute. Many other foods are commonly in capsule or tablet form. The form of products is not a basis for distinction in these proceedings and the post hoc effort for the first time on this appeal, to set up a distinction on this basis (Appellees' brief, pp. 44-45) is unjustified. The vitamin A and D regulations, on their face, moreover, apply to all oral preparations (JA 34a) without distinguishing their form in any respect.

The various attempted distinctions are moreover irrelevant to the issues before this Court. Appellees overlook and disregard the fact that as far as drug classification is concerned,

the issues in the instant proceeding are and were identical with those presented in the general vitamin regulations. Appellees' brief (p. 8), seeks to analyze in this respect the often-quoted paragraph of the statement by the Commissioner of the Federal Register of August 2, 1973 [38 F.R. 20723, JA 32(a)]. This Court has already specifically reviewed the Commissioner's statement and expressly noted that the Commissioner appeared to rely heavily, for the purpose of drug classification, on the prior general drug definition in the general vitamin regulations proceeding. (See 512 F.2d 703). Any reading of the Commissioner's statement must show that the Commissioner concluded that in his opinion, based on the findings in the general vitamin regulations, there was no nutritional use for vitamins A and D at levels higher than 10,000 I.U. and 400 I.U., respectively. He then concluded that they were "therefore appropriate for therapeutic purposes and thus properly classified as drugs." (JA 32a). (Emphasis added).

Appellees' brief also ignores another express statement by the Commissioner which was quoted in full in appellants' brief (P. 5), showing specifically that the Commissioner used the drug classification level of the general vitamin regulations as a threshold basis and support for these regulations:

> "The Commissioner finds no conflict between this drug regulation and the food regulations. All those vitamin A preparations within the ranges specified in §80.1 are considered foods and must be labeled as dietary supplements. Those preparations containing vitamin A in excess of the upper limit of these ranges but less than the proposed prescription drug levels are OTC drugs." 38 F.R. 20725 (JA 34a, col. 2-3)

The Commissioner in setting the even higher level for a prescription classification, thereby expressly stated that he was relying on the lower drug classification levels set forth in the general vitamin regulations as support for the drug status of these products. This Court, as well as the District Court,[7] understood that to have been the sole rationale previously expressed by the agency in this connection. Appellees' brief attempts to deny the above and points to distinctions without a difference. In terms of the issue of the drug definition and classification, the issue is not as to whether the Commissioner gave separate attention to the vitamin A and D regulations. The issue is as to whether there was a separate consideration for drug classification for these vitamins. The Commissioner's own statements referred to above indicate that there was not.

It is also simply beyond belief that the agency would now contend that the promulgation of these various regulations on the same date in August of 1973 was a coincidence. On that date, the agency issued a press release which indicates that the promulgation of these regulations was part of one single interrelated regulatory

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7 "The Commissioner has made the judgment, however, that vitamins are a food only when used within the limits of the recommended daily allowance. At such a level they, like ordinary foods, are 'nutrients.' Above those levels they are deemed 'appropriate only for therapeutic purposes and thus are properly classified as drugs" (38 Fed.Reg. 20723 (1973)).
NNFA v. Weinberger, 366 F.Supp. 1341 at 1345 (S.D.N.Y., 1973).

"package." A copy of this press release is set forth in an addendum hereto.[8] Moreover, the record now shows that the agency had first considered a prescription regulation (see 30 F.R. 11140 (August 28, 1965)) decided to withdraw such proposal during the pendency of the lengthy vitamin hearings (33 F.R. 9783 (July 6, 1968);JA 478a) and then, after the conclusion of the vitamin hearings and in virtual tandem with the proposed regulations thereunder, finally promulgated prescription requirements with significant cross-references to the other agency proceeding. (JA 32a)

The same agency has also previously conceded the interrelationship of these regulations by arguing (the reverse proposition) to this Court that Judge Frankel's original decision upholding the drug classification in this proceeding (NNFA v. Weinberger, 366 F.Supp. 1341) was dispositive of the same issue in the general vitamin regulations. See NNFA v. FDA, 504 F.2d at 788, n.33. A reading of the cited portion of Judge Friendly's decision shows that this Court clearly rejected Judge Frankel's original opinion and also recognized that the invalidation of the general drug definition would have the effect of precluding a prescription

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8 Although the agency voluntarily produced on the remand a copy of the original press release issued by the agency on December 14, 1972 (JA 509a), they did not include the press release which was issued with respect to the final regulations. This is a further indication of the impropriety of permitting appellees to unilaterally file the record in this proceeding and withhold from counsel, at their own discretion, documents which may be adverse to the agency's position.

classification. Id. text accompanying n. 33.

Appellees' arguments should not be permitted to obscure the fact that the agency, although given an opportunity by this Court, has failed to demonstrate, even by the Commissioner's own affidavit, that there was in fact separate consideration given to drug classification for vitamins A and D in this proceeding.

4.

APPELLEES MISCONSTRUE THE NATURE OF THE RECENTLY ENACTED VITAMIN AND MINERAL LEGISLATION

In light of the fact that Congress has recently spoken on the very question pending before this Court, it is important that the significance of the new statute be clearly set forth. The new legislation must be viewed in the context of the circumstances in which it was enacted. Beginning in 1973, the FDA, both in the general vitamin regulations and in the instant vitamin A and D regulations, sought to classify vitamins and minerals as drugs, based upon the FDA's assertion that beyond certain levels set forth in the U.S. RDA, there was no nutritional need or usefulness for such nutrients. This was the only reason ever given by the agency for insisting that vitamins and minerals beyond such levels were properly classified as drugs under the statute. In terms of the past history and construction of the food and drug statute, Appellants contended in this proceeding, as well as in the general vitamin regulations, that this approach by the agency violated the"intended use"provisions of the drug definition section

in the Act.

This Court invalidated the agency's general drug definition in 21 CFR §125.1(h) in part on the grounds that even based on the U.S. RDA,it could not be said as an objective matter that a given vitamin product could not be used for nutritional purposes. 504 F.2d at 788-789. The intended use doctrine was reaffirmed by this Court in Judge Friendly's decision as well as in Judge Mansfield's opinion on the prior appeal.

Under these circumstances, Congress stepped in to resolve the matter once and for all. The new legislation goes beyond the decisions of this Court in mandating that even if the Commissioner were to determine that there was absolutely no nutritional usefulness for a given potency of a vitamin or mineral, that there could not be a drug classification on that basis.

Congress was therefore very specific in the remedy it applied for the purpose of invalidating the only rationale ever previously expressed by the agency for automatic drug classification for vitamins and minerals.

Appellees seriously mischaracterize the nature of the legislative history of this statute. Their quotation from Senator Schweiker's statement in the Congressional Record, set forth at pages 11 and 12 of Appellees' brief, is misplaced. The statement, as a matter of law, is in error. Chapter 5 of the Food and Drug Act does not provide that a product is a drug merely because it is toxic. The statute in Chapter 2 contains a definition of the term "drug" in terms of intended use. [§201(g)(1)(B) 21 USC §321(g)(1)(B)].

In fact, Congress went to great efforts to indicate that the new legislation was not designed to otherwise change the provisions of the Food and Drug Act, and that a product was not to be considered a drug unless it was represented and intended for drug use. As noted by Congressman Rogers:

> "The provisions in the conference substitute would not alter the authority of the FDA to regulate these products as drugs under chapter V of the act if they are represented for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." (Cong.Rec. H3245 (daily ed. April 12, 1976). (emphasis added)

Similarly, the Conference Report cited in both Appellants' main brief and Appellees' brief expressly indicates that Congress recognized that drug regulation, even on a basis of safety, could only be made if "the high potency preparation of a vitamin or mineral is a drug as defined by §201(g) of the Act." (JA 622a, Appellees' brief, p. 11, Appellants' main brief, p. 12). In the face of this express indication in the Conference Report (which, as this Court has stated in this very proceeding (see 512 F.2d 699) is the most authoritative indication of legislative intent) Appellees' position must fail. In effect, Appellees urge this Court to permit a prescription drug classification even though the product does not come within the drug definition under the statute. The Court should be aware that Congress specifically and expressly rejected such an approach.

In one earlier version of the new legislation (set forth in the Addendum hereto at Add. 1-6) there was a proposal that FDA be permitted to classify a product as a drug merely because

it satisfied the prescription requirement of the statute. (Add. 3) Congress did not enact such a provision and the final version of the bill, as enacted into law and as amplified in the legislative history in the Conference Report, fully shows the congressional intent of maintaining the intended use standard of drug classification. The new legislation was enacted to restrict, rather than enlarge, FDA's authority in this area. The approach taken by Appellees is contrary to the rulings of this Court and would defeat the congressional intent in this respect. The final answer to Appellees' argument is that Congress did indeed intend that the FDA should retain its authority to regulate unsafe products, but that that authority should be exercised under the food provisions of the statute rather than by the impermissible drug classification attempted herein. The further significance of the new legislation is that it definitively invalidates the agency's latest rationale in terms of the USP. See discussion page 3, supra.

5.

THE ISSUE OF TOXICITY IS IRRELEVANT IN THESE PROCEEDINGS

On the prior appeal before this Court, Appellees attempted to argue that the toxicity of vitamins A and D in high dosage levels, was also a factor to be considered in sustaining the drug classification in these regulations. Appellees relied extensively on the very same medical articles which were then, as well as now,

before the Court. This Court remanded to the District Court with specific indications as to what factors should be considered from the point of view of drug classification. Toxicity, although extensively briefed and argued before this Court on the prior appeal, was not designated as a factor for the remand proceedings. The Agency, nevertheless, argued the same issue in the District Court, but Judge Frankel, too, did not take the question of toxicity into account for the purpose of drug classification. On this appeal, Appellees once again present the twice rejected argument that toxicity is a basis for establishing a drug classification. The impropriety and irrelevance of this issue has already been dealt with in Appellants' main brief, pages 13-15. By the Commissioner's own admission in his affidavit (JA 328a, 388a-389a), the food provisions of the statute are fully sufficient to deal with the question of harmful foods on the market place. It was, therefore, arbitrary, capricious and not in accordance with law to unnecessarily and without justification classify these products as drugs.

The agency, moreover, has never shown that the sale of any vitamin A and D product on the market place was dangerous per se. Instead, the rationale has always been that even safe products could be abused with the ingestion of astronomical amounts which might be toxic. Although this is a factor to be considered in determining PRESCRIPTION classification, it has no place in determining whether a product is a drug at all. This Court, as well as the District Court, recognized this aspect in the prior decisions herein.

Throughout these proceedings, the agency has refused to

reveal what analysis, if any, was ever made in terms of the medical literature as relates to the alleged toxicity. Presumably, this analysis is contained in the documents which have been withheld from counsel for Appellants pursuant to the decision of the District Court. Indirectly, however, the agency's analysis was in part revealed by a letter written by them in response to a question concerning vitamin A toxicity:

> "To respond to your specific questions, a single dose of over 2,000,000 IU of vitamin A can produce an increase in cranial pressure when administered to an adult, and a dose of over 350,000 IU can cause the same effect in an infant. Such symptoms are reversible. Continuous daily doses of 4,000-25,000 IU per kilogram of body weight for a period of six to fifteen months have been known to produce chronic toxicity."
> (See JA 623a)

By the agency's own analysis (which, despite earlier requests, was not included in the record) vitamin A toxicity symptoms relate to the ingestion of 4,000 IU to 25,000 IU per kilogram of body weight over a prolonged period of six to fifteen months. Accordingly, the range for potential adverse results in a 150 pound adult would be the ingestion of approximately 270,000 IU to 1,700,000 IU of vitamin A each day over a long period of time. Given this context, there is no basis for Appellees' loose references to danger of unspecified high dosages of vitamins A and D.[9]

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[9] The post hoc argument by counsel on this appeal that as little as 25,000 units of vitamin A could result in toxicity (Appellees' brief, p. 47) is therefore misplaced. These adverse results could occur only for an infant with a very low kilogram weight and has no relationship at all to products that are marketed for adults (See JA 241a). Significantly, the Commissioner's affidavit does not include this factually unsound argument.

Similarly, the citations in Appellees' brief, pages 43 and 44, also involve cases of astronomical ingestions of vitamins A and D. For example, the chart referred to in the articles which appear at page E-261 contains a listing of situations (not all of which involved toxic results) where the ingested levels of vitamin A were listed in the hundreds of thousands of units for the adults listed. Even in terms of toxicity, it is respectfully submitted that there is no basis for establishing a drug classification level at 10,000 and 400 IU when these levels have not been shown to bear any relationship to the levels at which adverse results may occur, particularly in relation to adults. The agency itself recognized that products could safely be sold above the 10,000 IU and 400 IU levels by including a provision in the preamble to the final regulations to the effect that no recall of existing stocks was deemed necessary. The regulations were made effective as of October 1, 1973, but applied only to products labeled after that date (JA 32a col. 1, ¶9). In fact, such previously labeled products were shipped in interstate commerce long after October 1, 1973 without any objection from the FDA. (JA 450a-452a, 506a).

In any event, as already noted, the statute itself makes no reference to toxicity as an element of drug definition and the statute provides separately for the handling and regulation of foods which are alleged to be toxic. See Appellants' main brief, pages 13-18.

THE RECORD BELOW WAS IMPROPERLY RESTRICTED BY THE DISTRICT COURT

Appellees (brief, pp. 21, 23) take the psoition that the record below was originally complete and that it did not need any supplementation. This position is in direct contradiction with the ruling of this Court. In explaining the reasons for the remand, Judge Mansfield has ruled, as Appellants argued on the prior appeal, that the entire record had not been submitted. This Court noted that it was not in a position to determine whether the drug classification herein was invalid because "it [does not] appear that we have been furnished with the entire record that formed the basis of the FDA's classification." 512 F.2d 702. This Court, therefore, requested that the entire record which formed the basis for the FDA's classification be included in the record. That basis, if any, has not been included in the record and, instead, documents have been withheld from Appellants by way of an assertion of privilege which was upheld in the District Court. It is not disputed that the withheld documents may be relevant (JA 526a) towards determining what the basis was or that they did in fact play a role in reaching a decision as to drug classification for vitamins A and D.

The cases cited in Appellees' brief (pp. 21-22) suggesting a limited record in a rule-making proceeding, are inapposite. None of these cases dealt with the question of what the full scope of the record should be and instead merely emphasized the fact that a "record" was in existence. Moreover, none of them involved an

Overton-type proceeding such as here.

In response to the extensive citations in Appellants' main brief (pp. 42-44), which show that the withheld documents are of a type which are frequently the focal point of judicial review of agency action (including rule-making),[10] Appellants respond by suggesting that they have here expressed their "willingness to be bound by the record created at the time the regulation was promulgated." Appellants' brief (p. 25).

It is respectfully submitted that this approach by the agency would frustrate all notions of effective judicial review. Surely, there cannot be one rule for one agency as opposed to another in terms of the question of when these type of documents may be withheld from the record. The approach taken by Appellees will leave the extent of the record in any given case subject to the whim of the "willingness" of the agency involved. In fact, even in this case, the agency mischaracterizes its willingness to be bound by the record in that they insist on relying, at least in part, on the extra record material contained in Commissioner Schmidt's affidavit. The agency's newly expressed willingness to be bound by the original record is manifestly a clear expression of their determination to avoid subjecting these regulations to closer scrutiny on the basis of the withheld documents.

It is in this context that the agency's invocation of executive privilege must be examined. The agency concedes (Appellants' brief, p. 26) that the case law decisions have heretofore

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[10] See, e.g., Dry Color Manufacturers Association, Inc. v. Department of Labor, 486 F.2d 98 at 108-109 (3d Cir. 1973).

required that a claim of privilege be interposed by the head of the agency involved. On this appeal, the agency asks this Court to formulate a new rule of law, citing (Appellees' brief pp.27-28, n.**) a proposed Federal Rule of Evidence 509 to the effect that an assertion of privilege for intra-agency memoranda should be permitted to be made by any attorney for the government. Appellees assert that it is unnecessary to engraft procedural safeguards with respect to this type of privilege.

The history of the proposed Federal Rules of Evidence suggests the exact opposite of what Appellees have proposed to this Court. In fact, it was originally proposed that a Rule 509 be enacted which would have permitted the assertion of this type of privilege by any attorney for the government.[11] Congress, however, rejected Rule 509 with the result that the current Federal Rules of Evidence contain only a single general rule as to privileges as found in Federal Rule of Evidence 501.

The legislative history of the congressional action with respect to the Federal Rules of Evidence clearly shows that Congress was very concerned by the problems of inappropriate invocation of privilege such as the one asserted in this case. In fact, one of the immediate concerns expressed when the matter was presented to the Congress was the fact that "any attorney for the Government"

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11 The proposed rule, however, also would have required that when the privilege is asserted, there be a specific showing that the disclosure of the documents would be contrary to the public interest. No such showing has been made in the instant case which involves only a blanket general invocation of the privilege.

could invoke the privilege under the proposal:

> "Mr. MOORHEAD of Pennsylvania: Mr. Chairman, I rise in support of this measure which will delay the effective date of the proposed Federal rules of evidence.
>
> * * * * * *
>
> "I would, however, like to comment on proposed rule 509, for the prospect of this rule alone being adopted is in my opinion sufficient reason to disapprove of the entire document. Proposed rule 509 would reverse the thrust of existing law, and in effect, grant a privilege to all Government documents unless the private citizen can meet a burden of proof for disclosure....
>
> "Under this proposed rule, any attorney representing the Government can object to the production of a record on the grounds that disclosure of the record would be 'contrary to the public interest.' As we well know, the 'public interest' is a vague standard subject to as many interpretations as there are persons interpreting."
> Congressional Record-House, March 14, 1973, pp. 7650-7651 (emphasis added)

Extensive hearings were held before a Subcommittee of the House of Representatives dealing with these issues. See, Hearings Before the Special Subcommittee on Reform of the Federal Criminal Laws of the Committee on the Judiciary, 93d Cong., 1st Sess., on Proposed Federal Rules of Evidence, Ser. No. 2 (1973) [hereinafter "House Hearings"]. Many prominent individuals and associations testified in vigorous opposition to the proposed Rule 509 of the Federal Rules of Evidence. Contrary to the position taken herein by Appellees (brief, p. 28), Judge Friendly of this Court testified:

> "Again, a matter that I am sure you are going to hear more about is Rule 509(c), where I limit myself to saying that whatever the right solution is, it does not seem to me that the exemptions of the Freedom of Information Act

are necessarily the proper measure of the bounds of what may be properly withheld by the Government at a trial." House Hearings, pp. 250, 264.

The Association of the Bar of the City of New York, presented extensive testimony in opposition to the proposed rule along the same lines and with respect to the issues relevant on this appeal noted in part:

> "D. Rule 509(c) - Who may claim the privi- for the Government, and the procedure for its assertion
>
> "Rule 509(c) provides that 'any attorney representing the government' may claim the Official Information privilege. For the reasons expressed by Chief Judge Reynolds in Thill Securities Corp. v. New York Stock Exchange... 1972 CCH Fed. Sec. L. Rep. ¶93,676 at p. 93,014 ..., we believe that only 'the chief officer of the government agency or department' involved should have the right to claim the privilege and make the appropriate showing....
>
> * * * * *
>
> "...The procedure recommended by Rule 509, in our opinion, would (1) encourage claims of privilege, not essentially to aid the interests of an executive department, but to aid the government's objectives in the lawsuit, and (2) increase the frequency of such claims." House Hearings, p. 140.

Similarly, a statement submitted on behalf of the Washington Council of Lawyers took serious exceptions to the aspects of proposed Rule 509 which the government relies on in this case:

> "The 'official information' privilege is also objectionable because it can be interposed by any attorney representing the government. The ease with which the privilege can be asserted virtually assures that the potential for delay will be realized.
>
> * * * * *

> "....Since this procedure would deny opposing counsel the opportunity to attack the claim effectively, the adversary system, the keystone of the litigative process, is effectively undermined. Any lawyer who has to litigate against the Government will find his job materially more difficult if this Rule ever becomes effective." House Hearings, pp. 186-187. (emphasis added)

In the face of these objections, Congress elected not to enact the proposed Rule 509 in order to maintain the earlier case law requirements which subjected any assertion of privilege to careful scrutiny and imposed stringent procedural safeguards to discourage improper and unnecessary assertion of such privileges.

It is respectfully submitted that the instant case is an excellent example of the need for maintaining rather than abolishing these requirements. Here the government has voluntarily produced some documents from its files, but, with respect to a limited number, has asserted the vague general privilege without an explanation as to why the disclosure of these documents would in any way be contrary to the public interest under the specific facts of this case. Appellees and the District Court assert that these documents should be considered presumptively privileged. (JA 569a)

In light of the case law and the congressional action with respect to this matter, the reverse should be true. The burden of asserting such privileges which may tend to prevent a full inquiry into the facts, should be on the government and it should not be lightly invoked merely to assist the government in arguing a case, as was done here. For this reason the procedural safeguards of requiring an affidavit from the head of the agency involved which explains the specific reasons why there should not be

a disclosure of the particular documents in question should be reaffirmed rather than abandoned. The public interest will not be served by the arbitrary withholding of documents to serve the narrow interests of the government in this particular litigation.[12]

7.

CROSS-EXAMINATION OF COMMISSIONER SCHMIDT SHOULD HAVE BEEN ALLOWED

Appellees' defense of the failure to allow cross-examination of Commissioner Schmidt is based on the untenable proposition that the original reasoning of the Commissioner of Food and Drugs as to drug classification of vitamins A and D was not based on the same premise as that advanced in the general vitamin regulations in connection with 21 CFR §125.1(h). (Appellees' brief, p. 19). This alone warranted examination of the Commissioner who, in his affidavit, completely ignored his own prior statement in the Federal Register of August 2, 1973, and made no effort to explain his apparent reliance on the invalidated general drug definition. Instead, counsel for the agency now argues that there was no such reliance in the first place, contrary to their own prior position and the express rulings of this Court and the District Court. (504 F.2d at 788, 512 F.2d at 703, 366 F.Supp. at 1345).

The only case cited by Appellees to support the refusal to allow cross-examination, Dunlop v. Bachowski, 421 U.S. 560 (1975),

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12 As noted in Appellants' main brief (pp. 39, 47), the District Court also erred in that it did not engage in a substantive examination of these documents in camera to determine their relevance in the instant case. See also JA 579a, n.4.

is completely inapposite. Dunlop involved a situation where a Secretary of Labor was vested with virtually absolute discretion as to whether or not to commence on his own litigation concerning irregularities in Union elections at the instance of a complaining Union member. Contrary to Appellees' assertion, the Court did not reject examination of the Secretary of Labor and, in fact, the Secretary of Labor conceded that there were situations in which judicial review might necessarily have to go beyond the confines of a statement of reasons given by the Secretary. Id., 421 U.S. at 574. The Court merely held that in light of the virtually absolute discretion of the Secretary it was difficult to imagine circumstances under which supplementation of a Secretary's statement of reasons would be necessary. Id. at 575. Interestingly enough, the Court noted that a statement of reasons "must be adequate to enable the Court to determine whether the Secretary's decision was reached for an impermissible reason or for no reason at all." Id. at 573. In the instant case, Commissioner Schmidt's affidavit is insufficient for this purpose and cross-examination of the Commissioner was in fact necessary. See, also, Schicke v. Romney, 474 F.2d 309 at 319 (2d Cir. 1973).

Appellees make much of the fact that the Appellants should not have been entitled to greater examination than would have been available if there had been a remand to the agency itself pursuant to Camp v. Pitts, 411 U.S. 138 (1973). Once again, Appellees miss the point. In Camp v. Pitts, supra, the Supreme Court explained the circumstances as to when a remand to the agency would be appropriate as opposed to the conduct of an Overton-type hearing.

The Court held that the validity of agency action must "stand or fall" on the propriety of the findings at the time of the agency action. The Court noted:

> "If that finding is not sustainable on the administrative record made, then the Comptroller's decision must be vacated and the matter remanded to him for further consideration." 411 U.S. at 143. (emphasis added)

In the instant case, this Court, despite the deficiencies of the Commissioner's explanation, decided not to vacate the agency's action, but, instead, directed that an Overton-type hearing be held in the District Court. If, as required by Camp v. Pitts, supra, the regulations had been vacated and remanded to the agency, the Commissioner would have been required to issue new proposals in the Federal Register and Appellants and the public at large would have had the opportunity of submitting and developing a full factual evidentiary basis to support their position. Under such circumstances (if the complete record would have been made available), there would not have been any need to examine the Commissioner. Under the circumstances here, the conduct of an Overton-type hearing, without permitting cross-examination, allowed the Commissioner to prevent a full inquiry as to the reasoning of the agency, thereby denying Appellants an opportunity to develop a full factual record in opposition.

Finally, it should be reiterated that Appellees have ignored one of the most significant aspects of the remand proceedings. Upon review of the Commissioner's affidavit, the District Court itself had at first directed that an examination of the Commissioner would be necessary (JA 532a-533a). It is respectfully submitted that the

District Court's reversal without explanation of its own decision that an examination was necessary under the circumstances, was improper and should be reversed.

8.

MISCELLANEOUS RESPONSES

The following additional matters are noted so that the background of this litigation is placed in its proper perspective:

A. Appellees' brief (p.5, n.*) argues that Judge Friendly's decision approved of Judge Frankel's original upholding of the drug classification as to vitamins A and D. As already noted, the agency argued to this Court that Judge Frankel's disposition was dispositive of the same issue presented in the general vitamin regulations. Judge Friendly expressly rejected the argument and also noted, in part, that Judge Frankel originally had reached his decision that the regulated products "in dosages above a given level were 'drugs' at all with a degree of ease dictated by...[his] view that they had properly been placed in the even more restrictive prescription category" and that it "was reached in the second opinion without explicit treatment." 504 F.2d at 788, n.33. It is difficult to understand how Appellees can characterize the foregoing as an "approving" reference.

B. Appellees suggest (brief, p.4) that the remand proceeding was not the result of any insufficiency in the agency proceedings. It is useful to set forth, briefly, the precise sequence of events had herein.

(i) On August 2, 1973, the agency promulgated the vitamin A and D regulations, citing and referring to a rationale to support drug classification which was identical to that set forth for general vitamin regulations drug classification (JA 32a).

(ii) On September 25, 1973, Judge Frankel originally upheld the agency's drug classification and rationale.

(iii) As part of judicial review in this Court, the agency argued that Judge Frankel's original decision in this case on drug classification was dispositive as to the same issue presented under general vitamin regulations (504 F.2d 788, n.33).

(iv) On August 15, 1974, this Court rejected the agency's "drug" position under the general vitamin regulations.

(v) In light of the foregoing, and because the record herein was not complete, this Court subsequently ordered a remand of this case to the District Court for the conduct of an Overton-type hearing. (512 F.2d at 761).

(vi) On the remand, no new record material to support the agency's drug classification was submitted, and relevant documents were withheld under a claim of privilege so that the "record" before this Court is now identical with the one before this Court on the prior appeal.

(vii) Appellees now argue (incorrectly) that the record herein was never incomplete and that despite the above, the Commissioner never relied on the invalidated drug definition for the drug classification herein.

CONCLUSION

For the reasons set forth in this Reply Brief and the Appellants' Main Brief, it is respectfully submitted that the decision of the District Court should be reversed.

Respectfully submitted,

BASS, ULLMAN & LUSTIGMAN
Attorneys for Plaintiffs-
Appellants

Of Counsel

Milton A. Bass
Jacob Laufer

ADDENDUM

93D CONGRESS
2D SESSION

H. R. 16317

IN THE HOUSE OF REPRESENTATIVES

AUGUST 7, 1974

Mr. KYROS (for himself. Mr. ROGERS, Mr. SATTERFIELD, Mr. PREYER, Mr. SYMINGTON, Mr. ROY. Mr. NELSEN, Mr. HASTINGS, Mr. HEINZ, and Mr. HUDNUT) introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish certain limitations respecting the authority of the Secretary of Health, Education, and Welfare to regulate certain foods for special dietary use under that Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. (a) Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by adding after section 409 (21 U.S.C. 348) the following new section:

"VITAMINS AND MINERALS

"SEC. 410. (a) (1) Except as provided in subsection (b)—

"(A) the Secretary may not establish maximum limits on the potency of any synthetic or natural vitamin or mineral within a food for special dietary use which is intended for ingestion in tablet, capsule, or liquid form;

"(B) the Secretary may not classify any vitamin or mineral as a drug solely on the basis of the potency of the vitamin or mineral; and

"(C) the Secretary may not limit the combination or number of any synthetic or natural—

"(i) vitamin,

"(ii) mineral, or

"(iii) other ingredient of food,

within a food for special dietary use which is intended for ingestion in capsule, tablet, or liquid form.

For purposes of this subsection and section 403, a food for special dietary use shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

"(2) A food for special dietary use which is intended for ingestion in tablet, capsule, or liquid form shall not be deemed under section 403 to be misbranded solely because its label bears, in accordance with section 403 (i) (2), all the ingredients in the food. The labeling and

advertising for any food for special dietary use which is intended for ingestion in tablet, capsule, or liquid form may not (A) list its ingredients which are not vitamins or minerals unless such ingredients (i) are listed in a list of all the ingredients of such food, or (ii) are subject to a regulation promulgated under section 403 (j), or (B) give prominence or emphasize the list of ingredients.

"(b) (1) Subsection (a) (1) shall not apply in the case of a vitamin, mineral, or other ingredient of food which is (A) deemed adulterated under section 402, or (B) represented for a use with respect to which the vitamin, mineral, or other ingredient is an unsafe food additive under section 409.

"(2) Subsection (a) (1) (B) or (a) (1) (C) shall not apply in the case of a vitamin, mineral, or other ingredient of food which—

"(A) the Secretary requires by regulations promulgated under section 503 (b) (1) to be dispensed only upon prescription, or

"(B) the Secretary determines is represented for use by children or pregnant or lactating women.

For purposes of subparagraph (B), the term 'children' means individuals who are under the age of twelve years.

"(c) (1) Vitamins, minerals, and other ingredients of food shall be subject to all other provisions of this Act

according to their terms, except as specifically provided by this section.

"(2) A food for special dietary use which under section 201 (g) is also a drug shall be subject to the provisions of chapter V according to its terms.

"(3) Subsection (a) (1) (A) shall not be construed to limit the authority of the Secretary to establish maximum limits on the potency of a synthetic or natural vitamin or mineral if such limits are prescribed in a regulation promulgated under section 503 (b) (1) requiring the vitamin or mineral to be dispensed only upon a prescription.

"(d) For purposes of this section, the term 'special dietary use' as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

"(1) Supplying a special dietary need that exists by reason of a physical, physiological, or other condition, including but not limited to the conditions of convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, diabetes mellitus, or the need to control the intake of sodium.

"(2) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

"(3) Supplying a special dietary need by reason

of being a food for use as the sole item of the diet.".

(b) The Secretary of Health, Education, and Welfare shall amend any regulation promulgated under the Federal Food, Drug, and Cosmetic Act which is inconsistent with section 410 of such Act (as added by subsection (a)) and such amendments shall be promulgated in accordance with section 553 of title 5, United States Code.

SEC. 2. (a) (1) Section 403 (a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343 (a)) is amended by inserting before the period at the end the following: "or, in the case of a food for special dietary use (as defined in section 410 (d)) which is intended for ingestion in tablet, capsule, or liquid form, its advertising is false or misleading in any particular".

(2) Section 403 (j) of such Act is amended by inserting after "label" the following: "(or in the case of a food for special dietary use (as defined in section 410 (d)) which is intended for ingestion in tablet, capsule, or liquid form, its advertising)".

(b) Chapter VII of such Act is amended by adding after section 706 (21 U.S.C. 376) the following new section:

"ADVERTISING OF A FOOD FOR SPECIAL DIETARY USE

"SEC. 707. Before initiating any action under chapter III with respect to any food for special dietary use which

is deemed to be misbranded under section 403 (a) or 403 (j) because of its advertising the Secretary shall consult with the Federal Trade Commission and, for the purpose of avoiding unnecessary duplication, coordinate such action with any action taken or proposed to be taken by the Commission under the Federal Trade Commission Act.".

(c) The amendments made by subsection (a) shall take effect one hundred and eighty days after the date of the enactment of this Act.

CODE: X = Opposed language
Numbers 1 to 9 = See NHF letter explaining numbered reasons for opposition.

93D CONGRESS
2D SESSION

H. R. 16317

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish certain limitations respecting the authority of the Secretary of Health, Education, and Welfare to regulate certain foods for special dietary use under that Act, and for other purposes.

By Mr. KYROS, Mr. ROGERS, Mr. SATTERFIELD, Mr. PREYER, Mr. SYMINGTON, Mr. ROY, Mr. NELSEN, Mr. HASTINGS, Mr. HEINZ, and Mr. HUDNUT

AUGUST 7, 1974
Referred to the Committee on Interstate and Foreign Commerce

Add. 7

NEW NEWS

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

73-34
PLEASE OBSERVE EMBARGO
FOR RELEASE: 10:00 AM
August 1, 1973

(Food and Drug Administration)
WALDEN--301-443-4177
(Home)--301-567-3148

The Food and Drug Administration today announced the third major phase of its long-range program to revise commercial food labeling practices as a means of improving nutritional information to the buying public.

Included in the package of 19 regulations, proposals and policy directives announced today are three final orders governing the definition, identity, formulation, and promotion of vitamin and mineral products. The new rules will apply to such products whether used as food supplements or as drugs.

Other regulations set strict labeling rules to prevent consumer deception from such products as fruit drinks that may contain no real fruit juice or "main dish" products lacking the principal or most expensive ingredient such as meat.

The regulations set guidelines for labeling imitation food products and establish microbiological quality standards for products such as ready-to-eat pies and food grade gelatin. Also included is a proposal to use the infant U. S. Recommended Daily Allowance (U.S. RDA) in nutrition labeling of baby foods. Notification is given that the Filled Milk Act, outlawed by a recent Supreme Court ruling, will no longer be enforced by the FDA.

-MORE-

FDA Commissioner Alexander M. Schmidt, M.D., termed the overall food labeling project a "landmark" in modern consumer protection initiatives by government.

He acknowledged strong opposition to the vitamin-mineral regulations and cited extensive misinformation and misrepresentation as the principal basis for continuing public confusion over the FDA action. He called on the press to help end this confusion.

Said Commissioner Schmidt: "The opposition with which we are most concerned stems from the honest fears of many citizens. Some fear that FDA is going to make certain vitamin pills unavailable or, if available, then only by prescription and at higher cost. Others fear that FDA may infringe on their right to decide what they will eat.

"None of this is true," he said, adding: "The single most important purpose and effect of the regulations is to require full and honest labeling and fair promotion of vitamin and mineral products as the basis for a more informed consumer choice.

"The new regulations are based on the best and broadest scientific evidence and expert advice that we can bring to bear.

"The regulations do not ban any vitamin or mineral from the market or force any manufacturer willing to provide proper formulation and labeling out of business.

"The regulations do not restrict any vitamin or mineral to prescription status only."

"Above all," continued the Commissioner, "The new regulations will not alter or interfere with the consumer's basic responsibility for deciding his own nutritional practices."

Commissioner Schmidt concluded: "I feel strongly that the time has come for this action. Ten years is long enough to study and debate. We will cheerfully abide by the judgments of the American consumer on the worth of our vitamin-mineral regulations. For, ultimately, the consumers' wishes will prevail. They alone must decide what kind and how much protection they wish from government."

# # #

A 202 Affidavit of Personal Service of Papers — LUTZ APPELLATE PRINTERS, INC.

FEDERAL COURT
SECOND CIRCUIT

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION, etal,

Plaintiffs-Appellants,

- against -

F. DAVID MATHEWS, etal

Defendants-Appellees

Index No.

Affidavit of Personal Service

STATE OF NEW YORK, COUNTY OF NEW YORK *ss.:*

I, Reuben A. Shearer *being duly sworn, depose and say that deponent is not a party to the action, is over 18 years of age and resides at* 211 West 144th Street, New York, New York 10030

That on the 10th *day of* January, *19*77 *at* One St. Andrews Plaza, New York, N.Y.

deponent served the annexed Reply Brief *upon* Robert B. Fiske, Jr.

the attorney *in this action by delivering a true copy thereof to said individual personally. Deponent knew the person so served to be the person mentioned and described in said papers as the* Yes *herein,*

Sworn to before me, this 10th *day of* January, *19* 77

Robert T. Brin

ROBERT T. BRIN
NOTARY PUBLIC, State of New York
No. 31-0418950
Qualified in New York County
Commission Expires March 30, 1977

Reuben Shearer

Reuben Shearer